A One Shot Deal: The National Childhood Vaccine Injury Act

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A ONE SHOT DEAL: THE NATIONAL CHILDHOOD VACCINE INJURY ACT

Andrew Clements is six years old. Like most other children his age, Andrew enjoys stuffed animals and the characters from Walt Disney's *101 Dalmatians*. Plastic decals of black and white spotted dogs adorn his bedroom walls, and furry, stuffed creatures cover his furniture. Any six-year-old would approve.

Yet Andrew's parents realize that their son has little more in common with other children his age. Andrew is not enrolled in elementary school. He cannot walk. He cannot talk. He cannot sit up without assistance. He cannot feed himself, but must be fed through a feeding tube. Although he recognizes their voices, Andrew cannot tell his parents what he thinks or how he feels.

Andrew was not born with disabilities. His difficulties began August 6, 1992, the day his mother took him for his six-month well-baby visit and Andrew received his third DPT vaccination. Later that evening, Andrew suffered his first seizure and was rushed to the hospital. By the age of three and a half, he had returned to the emergency room more than seventy times and experienced equally as many additional seizures. Between each seizure, Andrew appeared a happy and healthy child.

3. See id.
4. See id. at 21-22.
5. See id.
6. See id.
7. See id.
8. See id.
9. See id.
10. See id. at 11.
11. See id. at 12.
13. See id. at 13.
14. See id.
In the fall of 1995, the Clements’s family life changed permanently. Andrew suffered another seizure, which lasted more than four hours, and developed an infection that caused his body temperature to peak at 108 degrees.\textsuperscript{15} Although he recovered, Andrew never returned to being the relatively normal three-year-old he had been between each previous seizure episode.\textsuperscript{16}

In July of 1995, Andrew Clements’s parents filed a petition for compensation under the National Childhood Vaccine Injury Act (the Act).

Enacted in 1986, the Act created a no-fault compensation system through which parents could seek monetary relief for vaccine-related injuries suffered by their children.\textsuperscript{18} Because the Clements family blamed the DPT shot for their son’s injuries, they alleged that the vaccination was the cause-in-fact of Andrew’s encephalopathy and seizure disorder.\textsuperscript{19} Despite the Clements’s presentation of favorable evidence including testimony from a medical expert, the special master assigned to their petition denied the family’s claim.\textsuperscript{20}

This Note addresses both the motivation that prompted Congress’s passage of the National Childhood Vaccine Injury Act and its implementation since the Act’s passage in 1986. Ultimately, this Note suggests that the Act, as enforced, has not met Congress’s good intentions.

Part I discusses the purpose of the National Childhood Vaccine Injury Act, with particular regard to the history of immuni-

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\item \textsuperscript{16} See Allen, supra note 1, at 12.
\item \textsuperscript{17} See 42 U.S.C. §§ 300aa-1 to -34 (1994).
\item \textsuperscript{18} The Act divides into two parts. The National Vaccine Injury Compensation Program, which outlines the terms, requirements, and conditions under which petitioners may recover, became effective in 1988 and comprises the second portion of the Act. See infra notes 60-68 and accompanying text.
\item \textsuperscript{19} See Clements, 1998 WL 481881, at *1. Petitioners must meet several requirements in order to assert a claim under the Act. In addition to the basic requirements, petitioners may elect to claim either a Table Injury or a causation-in-fact injury. See infra notes 73-76 and accompanying text. Pursuant to the Act’s requirements, the Clements family claimed that (1) they had not collected an award or settlement from a civil action for damages caused by the vaccine, (2) their son had received his immunization in the United States, and (3) they had incurred more than $1,000 in unreimbursable medical expenses. See Clements, 1998 WL 481881, at *1.
\item \textsuperscript{20} See Clements, 1998 WL 481881, at *15.
\end{itemize}
izations in the United States and the potential shortage in availability of specific vaccines in the mid-1980s. Part II addresses the Act as a no-fault alternative to compensation, including the Act's pleading requirements and the role of the special master in determining whether recovery is appropriate. Part III focuses on the standard of proof required of petitioners in order to recover, with further emphasis on the special masters' role in adjudication of claims. Part IV concludes that Congress's initial goals in passing the National Childhood Vaccine Injury Act have not been met with respect to many petitioners. Although Congress has achieved its goal of ensuring a sufficient supply of vaccines, Part IV emphasizes that this victory has been realized only at the expense of efficiency and fairness. Although the no-fault compensation scheme has insulated the pharmaceutical industry from liability, it has not been an equal cure for individuals injured by vaccinations covered by the Act.

**HISTORY OF VACCINES**

The authority of states to require their citizens to be immunized against certain diseases and illnesses is well-settled. All fifty states and the District of Columbia have immunization requirements for children that must be met before they may attend public school. Due to the overwhelming success of vaccines in reducing the overall incidence of preventable illness, doctors and public health experts have referred to immunization

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21. See Jacobson v. Massachusetts, 197 U.S. 11, 38-39 (1905) (finding a compulsory state statute, which required all persons to be vaccinated against smallpox, a valid exercise of police power under the Constitution); Lisa J. Steel, Note, National Childhood Vaccine Injury Compensation Program: Is This the Best We Can Do for Our Children?, 63 GEO. WASH. L. REV. 144, 145 (1994).

22. See Randall B. Keiser, DÉJÀ Vu All Over Again? The National Childhood Vaccine Injury Compensation Act of 1986, 47 FOOD & DRUG L.J. 15, 15 (1992) (citing STAFF OF HOUSE SUBCOMM. ON HEALTH AND THE ENVIRONMENT OF THE HOUSE COMM. ON ENERGY AND COMMERCE, 99TH CONG., 2D SESS., REPORT ON CHILDHOOD IMMUNIZATIONS 1 (Comm. Print 1986)); Steel, supra note 21, at 144. Courts have recognized the validity of requiring immunizations prior to school entrance since the beginning of the twentieth century. See, e.g., Jacobson, 197 U.S. at 31-32 ("The principle of vaccination as a means to prevent the spread of smallpox has been enforced in many States by statutes making the vaccination of children a condition of their right to enter or remain in public schools.")
programs as one of "the single most effective [means of] health intervention." At the turn of the century, infectious disease proved to be among the greatest health risks threatening the world population. One hundred and sixty children per every one thousand births in the United States died as a direct result of an infectious disease.

The advent of comprehensive vaccination programs has all but eradicated specific illnesses or significantly reduced their incidence. Most recently, in 1993, Congress enacted a law providing free immunization for all eligible children. Known as the Childhood Immunization Initiative (CII), this law also increased state and local standards for vaccination rates among preschool age children. It set a three-year goal to have 90% of all children in the United States fully immunized by age two. By the 1996 target date, the CII had been modestly successful; thirty states and fourteen of the twenty-eight targeted urban areas had met the original requirements.

Societal Response

Despite comprehensive health programs and the undeniable health benefits achieved through immunizations, many children remain unvaccinated against the most preventable infectious diseases. 

23. Leslie K. Ball et al., Risky Business: Challenges in Vaccine Risk Communication, 101 PEDIATRICS, 453, 453 (1998); see also H.R. REP. NO. 99-908, at 4 (1986), reprinted in 1986 U.S.C.C.A.N. 6344, 6345 ("Vaccination of children against deadly, disabling, but preventable infectious diseases has been one of the most spectacularly effective public health initiatives this country has ever undertaken.").


25. See id.

26. See Keiser, supra note 22, at 15 (citing reductions in mortality rates from measles (2250 deaths in 1941 versus 2 in 1983), and reduced incidences of polio (57,000 cases in 1952 versus 4 in 1984) and pertussis (whooping cough) (265,000 cases in 1934 versus 2000 cases in 1982), as well as the global eradication of smallpox).

27. See 42 U.S.C. § 1396s(a)(1)(A) (Supp. 1998) ("[E]ach vaccine-eligible child . . . is entitled to receive the immunization without charge for the cost of such vaccine.").


29. See id.
Although a noble congressional effort, the CII has not served as a permanent motivational force. In 1998, fewer than one half of all two-year-olds were fully vaccinated. The lack of childhood immunizations has led to an average of 70,000 deaths per year due to vaccine-preventable illnesses.

Inadequate immunization rates among children may be due to parents' general misunderstanding about vaccination. Some parents may be unaware of the importance of immunizations, believing them to be unnecessary or a thing of the past. Conversely, other parents may be aware of the benefits of vaccinating their children against preventable illnesses, but may fear the potential adverse side effects associated with some vaccines.

Although not unfounded, their fears may be exaggerated. Beneficial to the vast number of recipients, vaccinations cause a small number of children to suffer significant adverse reactions. Complicating matters is the unforeseeable nature of such reactions. Certain physical conditions provide physicians with an indication that a child may have a greater propensity to react to a vaccine, but the potentially harmful side effects cannot be predicted with any certainty.

Ideally, a recipient will experience no reaction to a vaccine. The side effects displayed by those who do react vary greatly depending on the individual. More frequently, the recipient of a vaccine will experience local side effects, including redness and

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31. See id.
32. See id.
33. See id.
35. Advancements in vaccine technology have increased both the efficacy and safety of immunizations. For instance, medical professionals favor the injected poliovirus vaccine (IPV) over the oral polio vaccine (OPV). See Geoffrey Evans, Vaccine Liability and Safety Revisited, 152 ARCHIVES OF PEDIATRICS AND ADOLESCENT MED. 7 (Jan. 1998), available in 1998 WL 12035636. Furthermore, the more dangerous whole-cell pertussis vaccine has all but completely yielded to the newer acellular pertussis vaccination (DTaP). See id.
swelling around the injection sight, or mild systemic responses, including drowsiness and occasional vomiting.\textsuperscript{38} Some vaccines cause significantly more harmful and severe reactions.\textsuperscript{39} Though infrequent, recipients may experience significantly elevated body temperatures, enter a shock-like state, or in some cases suffer convulsions and encephalopathy.\textsuperscript{40} In the most rare situation, a child may die from a vaccine.\textsuperscript{41}

The risks that vaccines present may be accorded greater weight by parents than appropriate. More than 100 million doses of vaccines are issued every year to American children.\textsuperscript{42} Yet in 1997, fewer than 100 children died as the direct result of receiving an immunization.\textsuperscript{43} Nonfatal reactions are similarly scarce; DPT injections carry the greatest risk among childhood vaccinations, with recipients standing a one in one hundred thousand chance of suffering permanent brain damage.\textsuperscript{44} The recent advent of safer vaccines has reduced further the risks involved.\textsuperscript{45}

The individual risks and potential societal consequences of an unimmunized population are far greater than those posed by the vaccinations themselves.\textsuperscript{46} Parents unwilling to face the poten-

\textsuperscript{38} See Diptheria, Tetanus, and Pertussis, Nurse Practitioner, July 1996, at 94-96 [hereinafter Diptheria] (describing adverse reactions to DPT immunizations to include local reactions of redness, swelling and pain, and systemic reactions to include drowsiness, fretfulness, vomiting, and anorexia).


\textsuperscript{40} See Diptheria, supra note 38, at 94-96 (listing the more severe reactions children may experience after receiving DPT immunization injections).

\textsuperscript{41} See Schultz, supra note 34, at 65.

\textsuperscript{42} See id. The Center for Disease Control (CDC) recommends that children receive six vaccines by the age of six: Hepatitis B; Diptheria, Pertussis (whooping cough), and Tetanus (DPT); H influenza type B; Polio; Measles, Mumps, and Rubella (MMR) (German measles); and Varicella. See id. More recently, experts have recommended an oral vaccination against rotavirus, which serves as the leading cause of gastroenteritis in small children. See Marilyn Chase, Authorities Are Urging a New Series of Shots to Keep Kids Healthy, WALL ST. J., Jan. 25, 1999, at B1.

\textsuperscript{43} See Schultz, supra note 34, at 65.

\textsuperscript{44} See id.

\textsuperscript{45} In particular, the development of a safer acellular DPT vaccine has reduced the health risks posed by its predecessor, a whole cell vaccine. See Allen, supra note 1, at 22. An inactivated and injectable alternative to the orally administered live polio vaccine, which can cause paralysis, also has been made available. See Schultz, supra note 34, at 65.

\textsuperscript{46} The Vaccine Adverse Event Reporting System receives approximately 10,000
tial adverse consequences of immunizing their children may assume their children are not at risk for exposure to vaccine-preventable illnesses because other children are immunized.\textsuperscript{47} To the contrary, outbreaks of measles and pertussis in unvaccinated persons have been documented in the last decade.\textsuperscript{48}

\textit{Pharmaceutical Industry}

For several decades, the risk inherent to immunization remained relatively static until the recent development of safer vaccines.\textsuperscript{49} Ironically, as the safety of vaccines has increased, so has public awareness of the potential adverse side effects. For example, the pharmaceutical industry came under sharp public criticism due, in part, to the 1982 television documentary, “DPT Vaccine Roulette.” This documentary garnered significant media attention and earned an Emmy nomination for its depiction of children who suffered from irreparable neurological disabilities after receiving DPT vaccinations.\textsuperscript{50}

As a result of the increased media attention and public awareness, individuals who suffered adverse reactions from vaccines began suing the pharmaceutical companies that produced the drugs.\textsuperscript{51} In turn, the pharmaceutical companies increased the prices of the vaccines they produced.\textsuperscript{52} Some companies no longer

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\item complaints per year regarding the more than 100 million vaccinations administered to patients in the United States. See Gail Kachadourian, \textit{Vaccinations: Why Some Parents Say No}, DETROIT NEWS, Dec. 8, 1998, at F6, \textit{available in} 1998 WL 23631753. Of the complaints received, fewer than 15% describe serious events. See \textit{id.} The vast majority, comprising more than 85% of all cases reported, describe events such as swelling at the site of injection or low-grade fevers. See \textit{id}. Gaps in childhood immunizations, however, can lead to potentially catastrophic outbreaks of preventable illness. For instance, between 1974 and 1976 immunization with the pertussis vaccine in Japan dropped from 80% to 10% due to governmental concerns pertaining to the whole-cell vaccine. See Allen, \textit{supra} note 1, at 22. Three years later, Japan experienced an epidemic. See \textit{id}.\textsuperscript{47}
\item See Schultz, \textit{supra} note 34, at 65.\textsuperscript{48}
\item See \textit{id}. (noting that a measles outbreak in the early 1990s caused at least 21 deaths in the United States).\textsuperscript{49}
\item See \textit{supra} note 26 and accompanying text.\textsuperscript{50}
\item See Evans, \textit{supra} note 35, at 7. The documentary received harsh reviews from the medical establishment, including the American Academy of Pediatrics. See \textit{id}.\textsuperscript{51}
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could justify financially the manufacture of specific drugs that had become the target of increasing numbers of civil suits.\footnote{By 1986, few pharmaceutical companies remained willing to produce childhood vaccines. Only two companies continued to produce DPT vaccines and only one company manufactured the polio vaccine. Facing a potentially severe shortage in available vaccines, a decline in the number of immunized children, and the pleas of the uncompensated victims of vaccination injuries, Congress enacted the National Childhood Vaccine Injury Act.} By 1986, few pharmaceutical companies remained willing to produce childhood vaccines.\footnote{See id., reprinted in 1986 U.S.C.C.A.N. at 6348. Plaintiffs filed 24 civil actions against pharmaceutical companies in 1980 for vaccine-related injuries; by 1985, an average of 144 new cases were filed every year. See Theodore H. Davis, Jr. & Catherine B. Bowman, No-Fault Compensation for Unavoidable Injuries: Evaluating the National Childhood Vaccine Injury Compensation Program, 16 U. DAYTON L. REV. 277, 296-97 & nn.126-28 (1991).} The Secretary of Health and Human Services is responsible for the program and selects a director to ensure its proper administration.\footnote{See H.R. REP. No. 99-908, at 4, reprinted in 1986 U.S.C.C.A.N. at 6345.} The director must administer the program according to the goals established by Congress.\footnote{See id., reprinted in 1986 U.S.C.C.A.N. at 6348. Two additional states, Massachusetts and Michigan, produced their own DPT vaccines. See id.}

The Act itself consists of two parts. Part I establishes the National Vaccine Program.\footnote{See 42 U.S.C. §§ 300aa-1 to -34 (1994).} This program enables the director to coordinate vaccine research programs, vaccine safety and efficacy testing, vaccine distribution and requires her to ensure

\footnote{See H.R. REP. No. 99-908, at 7 (1986), reprinted in 1986 U.S.C.C.A.N. 6344, 6348 (referring to the “inadequacy . . . of the current approach to compensating those who have been damaged by a vaccine” and “the instability and unpredictability of the childhood vaccine market”).}
the overall effectiveness of vaccine immunization programs.\textsuperscript{61} Part II establishes the National Vaccine Injury Compensation Program.\textsuperscript{62} This program defines the terms and conditions by which a person who has suffered a vaccination injury may seek compensation.\textsuperscript{63}

\textit{National Vaccine Injury Compensation Program}

The National Vaccine Injury Compensation Program created a no-fault alternative to state tort remedies. Specifically, the "bill establishe[d] a compensation system for those persons injured by routine pediatric vaccines."\textsuperscript{64} Intended to be both "expeditious and fair,"\textsuperscript{65} the Act created "a scheme of recovery designed to work faster and with greater ease than the [states'] civil tort system."\textsuperscript{66} By eliminating the need for plaintiffs to demonstrate either a defendant-manufacturer's negligence in producing or marketing the drug, or a vaccine's defectiveness, Congress hoped the federal alternative would reduce the number of civil actions filed in state court.\textsuperscript{67}

This federal program preempts action in state court, but does not preclude state court action. In order to ensure that fewer plaintiffs pursue state court remedies, the Act requires a prospective plaintiff to file a petition and follow its enumerated procedures before pursuing a remedy in a state court.\textsuperscript{68}

\textsuperscript{61} See id. A detailed analysis of the first part of the Act is beyond the scope of this Note. For a critical discussion of the first part of the Act, see Phillip K. Russell, \textit{Development of Vaccines to Meet Public Health Needs: Incentives and Obstacles}, 7 RISK: HEALTH, SAFETY & ENV’T, 239, 250 (1996).
\textsuperscript{62} See 42 U.S.C. §§ 300aa-10 to -17 (1994)
\textsuperscript{63} See id.
\textsuperscript{65} Id.
\textsuperscript{68} See 42 U.S.C. § 300aa-11(a)(2)(A) (1994). The Act precludes petitioners from seeking redress in state court for unspecified damages or damages greater than $1,000 until the petition has been adjudicated fully in accordance with the Act's requirements. See id.; see also Schafer v. American Cyanamid Co., 20 F.3d 1, 2 (1st Cir. 1994) (discussing the relationship between the Act and the traditional methods of tort recovery).
Process and Procedure

If a person wishes to seek compensation under the Act, he or she must file a petition with the United States Court of Federal Claims (previously known as the United States Claims Court) and serve it upon the Secretary of Health and Human Services. After filing and service, the clerk of the court must direct the petition to a chief special master who then will assign the case to another special master. The special master assigned to the petition is responsible for determining whether recovery under the Act is appropriate.

A petition must meet several requirements before the special master will consider whether to compensate the plaintiff under the Act. First, the petition must contain affidavits and documentation that demonstrate the petitioner received a vaccine listed on the Act's "Vaccine Injury Table." The Table contains both a list of recognized vaccine-caused injuries as well as a list of the specified time periods when a vaccine-caused injury must present itself in order to be recognized as a Table injury. If the petitioner demonstrates that the vaccine caused a Table injury within the specified time period, then the petitioner is entitled to a presumption of causation. If the petitioner cannot demonstrate that the vaccine caused an injury specified by the Table or cannot show a manifestation of symptoms within the time frame recognized by the Table, then the petitioner must demonstrate, by a preponderance of the evidence, that the recognized vaccine was the cause-in-fact of the adverse reaction.

71. See id.
72. See infra notes 92-101 and accompanying text (providing details of the special masters' role in claims adjudication).
74. See Vaccine Injury Compensation, 42 C.F.R. pt. 100.3 (1998) (providing the most recently revised Vaccine Injury Table).
76. See 42 U.S.C. § 300aa-11(c)(1)(C) (1994); see also Terran, 41 Fed. Cl. at 333.
The special master who presides over each case ultimately determines whether to award the petitioner compensation. Should the special master determine that compensation is appropriate, then the petitioner may recover not only medical expenses that cannot be reimbursed and that were incurred prior to receipt of judgment, but also expected future medical expenses. In addition, the special master may award lost earnings, damages for pain and suffering that do not exceed $250,000, and reasonable attorneys' fees and costs. If the petitioner has died as a direct result of a vaccine injury, the special master may award no more than $250,000. The Act specifically precludes the award of punitive and exemplary damages.

**RELATIVE LACK OF SUCCESS**

Consistent with one congressional goal, the Act has succeeded in reducing the amount of state court litigation involving the pharmaceutical industry. The Act has failed, however, to

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80. See id. § 300aa-15(a)(4).

81. See id. § 300aa-15(e). Note that a special master may award attorneys' fees and costs when a petitioner is denied compensation as long as the special master find the petitioner filed the claim in good faith and on a reasonable basis. See id.

82. See id. § 300aa-15(a)(2).

83. See id. § 300aa-15(d)(1).

84. See Bureau of Health Professions, U.S. Dep't of Health & Human Servs., Background Information on VICP (last modified Sept. 13, 1999) <http://www.hrsa.dhhs.gov/bhp/vicp/advic.htm>. DTP suits filed against manufacturers reached an all-time high in 1986. Between 1986, the year Congress enacted the Act, and 1994, the number of suits filed against members of the pharmaceutical industry decreased dramatically. In 1986, more than 250 lawsuits were filed against manufacturers of DTP vaccines. See id. From 1990 to 1997, petitioners averaged fewer than twenty suits per year. See id. In 1997, petitioners filed only four lawsuits. See id. In addition to suits filed against manufacturers, the number of suits filed against physicians and other health care professions for vaccine-induced injuries also has de-
achieve another equally important goal of Congress; to facilitate petitioners' recovery for vaccine-related injuries.

An initial review of the Act can be deceiving with respect to the latter goal. Between 1988 and 1999, petitioners filed a total of 5717 claims in accordance with the Act's requirements. A total of 4969 cases have been adjudicated to date, and special masters have awarded over $1 billion in damages and attorney's fees. In total, more than 1300 petitioners received compensation in accordance with the terms and conditions of the Act.

Despite the size of these numbers, more than two-thirds of all claims filed by petitioners ultimately are dismissed. Both the overwhelming authority of the special masters and the causation requirements of the Act have caused the majority of persons injured by vaccines to be denied compensation.

Although the Act has promoted consistency with respect to the number of claims dismissed, in no other regard may its implementation be considered fair to petitioners. More often than not, petitioners denied compensation under the Act remain uncompensated. Not only does the Act delay the filing of civil actions (and therefore delay the receipt of compensation), but it also hurts many petitioners who will likely be unable to recover in state court. As Congress noted when it enacted the federal no-fault alternative, plaintiffs in state courts have great difficulty demonstrating that a manufacturer behaved negligently or that a vaccine itself was defective.

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86. See id.

87. See id. (listing a total of 1493 compensated claims).

88. See id. (listing a total of 3516 dismissed claims).

89. See id.

90. See infra note 91 and accompanying text.

91. See H.R. REP. No. 99-908, at 12 (1986) (stating that the Act "is also intended to compensate persons with recognized vaccine injuries . . . without a demonstration that a manufacturer was negligent or that a vaccine was defective"), reprinted in 1986 U.S.C.C.A.N. 6344, 6353.
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Special Masters

The overwhelming discretion held by the special master in each petition filed under the Act represents one of the flaws inherent in the Act. After a petition is filed, a chief special master is responsible for distributing the claims to one of seven other special masters. The special master assigned to the claim has complete jurisdiction over the initial proceedings. Moreover, the means of selecting special masters compounds the effects of their unbridled discretion. The majority of the judges seated on the United States Federal Claims Court appoint each special master to a four-year term. Once chosen, special masters may be removed only for incompetence, misconduct, neglect of duty, or physical or mental disability.

Petitioners' Counterbalances

The selection process for special masters, which facilitates their entrenchment, is not without a counterbalance for petitioners. Should a special master deny compensation, a petitioner may move for a review of the decision by the United States Court of Federal Claims within thirty days of the special master's rejection. The Court of Federal Claims then has 120 days from the filing of a response to complete its action, subject to a ninety-day suspension period should it choose to remand the case to the special master. If the petitioner remains dissatisfied with the decision of the Court of Federal Claims, the petitioner may appeal to the United States Court of Appeals for the Federal Circuit within sixty days of the lower court's ruling.

93. See id. § 300aa-12(a).
94. See id. § 300aa-12(c)(4).
95. See id. § 300aa-12(c)(2).
96. When a petition before the special master or the Court of Federal Claims requires more than 420 days (subject to additional suspension periods), the special master or the court must notify the petitioner of his or her right either to withdraw the claim or to elect to maintain the claim before the special master. See id. § 300aa-12(g)(2).
97. See id. § 300aa-12(e). Both the plaintiff and the Department of Health and Human Services retain the right to move for review. See id. Once either party so moves, the respondent then has 30 days to file a response. See id.
98. See id. § 300aa-12(e)(2).
99. See id. § 300aa-12(f). Petitioners cannot seek review by the Court of Appeals.
As a second counterbalance to the special masters' authority, a petitioner may file a subsequent civil action in state court. Should the petitioner either receive no award, or believe the damages awarded are insufficient, the petitioner may choose to reject the decision of the special master. Although the Act precludes the initiation of a civil action concurrent or prior to the filing of a petition with the Court of Federal Claims, a petitioner's rejection of the special master's decision triggers that petitioner's right to pursue a remedy in state court.

Insufficient Recourse

The Act's requirement of efficiency is not concomitant with the notion of fairness to petitioners. The time limitations that petitioners may expect, and that the courts must meet, appear to achieve the efficiency prong of Congress's aim to ensure the "expeditious and fair" compensation of vaccine-injured persons. Although the time limitations make the process more expeditious, they do not make it any more fair. The court's efficiency does little to curtail the authority of the special masters.

The highly deferential standards of review that courts use contribute to the failure of the present system to afford petitioners the fairness Congress intended. Courts will reverse the decision of a special master only with a finding that the special master abused his or her discretion with respect to the original petition. In reviewing the special master's holding, the federal claims court may set aside the ruling only if the decision is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." The standard ensures a highly defer-
The standard of review employed by the court of appeals compounds the deference afforded the special master by the federal claims court. Should the special master deny compensation and the federal claims court affirm the judgment, then the petitioner appealing to the Federal Circuit Court of Appeals encounters further obstacles. The statute itself imposes no standard of review for the Federal Circuit Court of Appeals. In *Munn v. Secretary of the Department of Health and Human Services*, however, the court determined that the decision of the federal claims court deserves the same deferential review as does the special master’s determination. The court justified its decision stating that “[a]ny other standard would create an anomalous situation ... in which the affirming decision (the Claims Court’s judgment) [is] more readily overturned than the original decision (that of the special master).”

Anomalous situations notwithstanding, the deferential review afforded the special master by the federal claims court and the Federal Circuit Court of Appeals virtually ensures that the special master’s findings will not be disturbed on appeal. The fact that reasonable persons might differ with the special master’s conclusion is insufficient to warrant reversal. The appeals courts will affirm the decision as long as the special master articulates a rational basis for his or her decision.

105. See *Munn v. Secretary of the Dep’t of Health & Human Servs.*, 970 F.2d 863, 869 (Fed. Cir. 1992) (describing the review as one that gives “the special master’s determinations decisional effect” and “is highly deferential to the factual findings of the special master”).

106. *See id.*


108. *See id.* at 870.

109. *Id.* at 871.

110. See *Schwenk v. Secretary of the Dep’t of Health & Human Servs.*, No. 91-5133, 1992 WL 28022, at *2 (Fed. Cir. Feb. 14, 1992) (“That reasonable individuals might reach different conclusions ... is not a sufficient ground for reversal.”).

111. See *Walker v. Secretary of the Dep’t of Health & Human Servs.*, 33 Fed. Cl.
In an environment in which the factual determinations of the special master are of critical importance, the standard of review has created a situation in which the Act's enforcement is inimical to Congress's intent. Affording special masters "the most deferential [review] possible"\textsuperscript{112} contravenes Congress's intent to ensure the fair adjudication of claims for vaccine-injured persons.

**The Burden of "Fairness"

The burden of persuasion that the petitioner bears in his or her petition for compensation exacerbates the fairness problems posed by the deferential review. The Act requires that each petitioner demonstrate a vaccine-related injury.\textsuperscript{113} The petitioner is entitled to a presumption of causation if he or she can demonstrate that a Table-recognized injury followed the administration of a vaccine listed on the Vaccine Injury Table within the time specified in the Table.\textsuperscript{114} If the petitioner can demonstrate only that he or she received a Table-recognized vaccine, the petitioner must show by a preponderance of the evidence that the vaccine caused the complained of injury.\textsuperscript{115} A petitioner must sustain this burden through the presentation of either medical records or expert testimony.\textsuperscript{116}

**Causation and Special Masters

That petitioners must prove the causation element in order to receive compensation may at first seem reasonable. The broad

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\textsuperscript{97}, 100 (1995); see also, e.g., Hovey v. Secretary of the Dep't of Health & Human Servs., 38 Fed. Cl. 397, 402 (1997) (upholding a special master's decision to deny an evidentiary hearing and dismiss a petition when the special Master "thoroughly weighed the evidence and reached a factually supportable conclusion"), appeal dismissed, 135 F.3d 773 (Fed. Cir. 1997).


\textsuperscript{113}. See supra notes 73-76 and accompanying text.

\textsuperscript{114}. See supra notes 73-75 and accompanying text.

\textsuperscript{115}. See supra note 76 and accompanying text.

\textsuperscript{116}. See 42 U.S.C. § 300aa-13(a)(1) (1994); see also Buxkemper v. Secretary of the Dept't of Health & Human Servs., 32 Fed. Cl. 213, 220-22 (1994) (summarizing the evidentiary requirements a petitioner must meet in order to satisfy the Act's standard of proof).
discretion of the special master, however, nullifies any reason-
ableness granted to petitioners by the flexible, alternative means
of demonstrating an injury. As discussed above, under the latter
alternative, the petitioner must prove causation in the statutory
scheme. The petitioner must submit “evidence that makes the
existence of a contested fact more likely than not.”117 The proba-
bility that a fact exists in the petitioner’s favor is not sufficient
to establish it as true.118 Rather, the special master “must be-
lieve that the existence of a fact is more probable than its non-
existence, before the [special master] may find in favor of the
party who has the burden to persuade.”119 Despite the existence
of guidelines that the special master must consider when evalu-
ating each petition,120 no other factors militate against the “vir-
tually unreviewable” determinations of the special master.121

The Act attempts to provide fairness to petitioners, but falls
short. It requires special masters to “afford all interested per-
sons an opportunity to submit relevant written information,”122
and to consider all relevant and reliable evidence.123 Neverthe-
less, the Act provides few additional guidelines for special mas-
ters. The Act does not require special masters to hold evidentiary
hearings,124 nor does it bind them to federal common law or

118. See Thornton, 35 Fed. Cl. at 440.
120. See 42 U.S.C. § 300aa-13(b)(1); see also Thornton, 35 Fed. Cl. at 440-41 (listing the guidelines provided in the Act as relevant considerations for the special master).
123. See id. at 400-01 (citing Vaccine Rules of the Office of Special Masters, in RCPC app. J).
124. See Burns v. Secretary of the Dep’t of Health & Human Servs., 3 F.3d 415, 417 (Fed. Cir. 1993); Hovey, 38 Fed. Cl. at 400-01 (noting that the Vaccine Rules accord special masters extensive discretion in conducting proceedings).
statutory rules of evidence.\textsuperscript{125} The Act requires merely that special masters abide by the Vaccine Rules and provide "each party [with] a full and fair opportunity to present its case."\textsuperscript{126}

\textit{The Vaccine Injury Table}

For its part, the Vaccine Injury Table does not temper the discretion that the special masters hold. Whether petitioners attempt to demonstrate a Table injury within the time specified in the Table or attempt to prove actual causation, the Table is both over-and under-structured to meet Congress's fairness goal.

An initial review of the Table does not indicate its inherent problems. First, the Table itself has not remained static.\textsuperscript{127} In passing the Act, Congress recognized that future medical discoveries would challenge the efficacy of the Table in providing fair recovery for petitioners.\textsuperscript{128} To address such issues, Congress authorized the Secretary of Health and Human Services to amend the Table as needed.\textsuperscript{129} Such amendments are to be based on the research and published findings of the Institute of Medicine (IOM), a division of the National Academy of Science, and the Advisory Commission on Childhood Vaccines (ACCV).\textsuperscript{130}

Composed of health care professions, legal experts, federal officials, and interested citizens (including several parents of vaccine-injured children), the ACCV retains a statutorily created ninety-day comment period for each revision proposed by the Secretary.\textsuperscript{131}

In addition to the statutorily created review committees that are designed to achieve some semblance of fairness in the Table, the Secretary designated several committees to serve as addi-

\begin{itemize}
\item \textsuperscript{125} See Hovey, 38 Fed. Cl. at 400.
\item \textsuperscript{126} Id. at 401 (describing the Vaccine Rules of the Office of Special Masters, in RCFC app. J).
\item \textsuperscript{127} See O'Connell v. Shalala, 79 F.3d 170, 173 (1st Cir. 1996).
\item \textsuperscript{128} See id. ("[T]he first iteration of the Table was not perfect... [T]he solons knowingly used incomplete data when forging the causal links between vaccines and associated medical conditions.").
\item \textsuperscript{129} See 42 U.S.C. § 300aa-14(c)(3) (1994).
\item \textsuperscript{130} See id. § 300aa-19; see also O'Connell, 79 F.3d at 173-74 (describing the IOM and the ACCV).
\item \textsuperscript{131} See O'Connell, 79 F.3d at 173-74.
\end{itemize}
tional resources. The Secretary created the Public Health Service Task Force and enlisted the aid of the National Vaccine Advisory Committee (NVAC) in order to ensure an accurate and effective Table. Nevertheless, despite Congress's and the Secretary's goals in implementing the advisory committees, the Table's structure remains an ineffective means of compensating victims.

First, the Table is overstructured. The Table provides a list of vaccines compensable under the Act, the symptoms recognized as an injury caused by the specific vaccines, and the time period within which the bona fide symptoms must manifest themselves in the injured person. Theoretically, this system of concomitant requirements should ensure greater consistency among different claims. Nevertheless, it does not create a fair system of recovery. Particularly with regard to the timing elements, a petitioner may be able to demonstrate a vaccine injury, but not be able to demonstrate that the injury occurred within the exact specified time. For instance, in Ultimo v. Secretary of the Department of Health and Human Services, the special master ruled that a child who suffered from seizures approximately 78-

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132. See id.
133. See id. at 174-75. NVAC differs from the ACCV in its advisory capacity to the Secretary. The former serves in a more general capacity by advising the Secretary about national programs for vaccine-education and immunization. See id. The latter's role is reserved specifically for consideration of compensation issues. See id.
134. The Vaccine Injury Table is supplemented by the Qualifications and Aids in Interpretation (QAI), which provides detailed explanations and definitions of the terms identified in the Table. See 42 U.S.C. § 300aa-(14)(b) (1994); O'Connell, 79 F.3d at 173.
136. For instance, a petitioner who claims that a whole-cell pertussis vaccine induced anaphylactic shock in the recipient of the vaccine must demonstrate that the reaction occurred within four hours of the injection. See 42 C.F.R. § 100.3 (1998). Similarly, a petitioner wishing to show that the immunization induced encephalopathy must demonstrate that the onset occurred within 72 hours after the injection. See id. A petitioner who cannot demonstrate that a recognized Table injury occurred within a recognized Table time is not entitled to a presumption of causation. Accordingly, if the petitioner can demonstrate that anaphylactic shock occurred five hours after an injection, but not four, he or she must pursue recovery under the latter method.
80 hours after receiving a vaccination did not meet the "3 day" time period required by the Table. 138

Ironically, the special master, who retains considerable discretion in almost every element of the Act's enforcement, has no discretion with respect to the Table. 139 A petitioner must attempt to show the more difficult standard of actual causation if he or she cannot meet the Table requirements. 140 Accordingly, petitioners receiving identical vaccines with identical injuries may have to pursue different methods of recovery for any one of several reasons. First, one petitioner's injury may have manifested itself within the time period recognized in the Table, entitling that person, but not his almost identically situated counterpart, to a presumption of causation. Second, two petitioners may have the same recognized injury, manifested within the same time, but one may be ineligible for the presumption because the Secretary has since narrowed the Table. 141

POTENTIAL ALTERNATIVES

Few can doubt the present ineffectiveness of the National Childhood Vaccine Injury Act. Neither Congress's goal to ensure the efficiency with which vaccine-injured persons can recover for their injuries nor its attempt to increase the fairness in that process has been met.

Underlying the Act's substantive problems is the fact dependent nature inherent to each petition. Whether a petitioner

138. See id. at 150-51. At the time of the decision, the Table specifically designated a "3 day," rather than a "72 hour" time frame. Id.
140. The latter alternative is more difficult because, as mentioned previously, the petitioner is not entitled to a presumption of causation.
141. The Secretary's revision of the Table with respect to DPT illustrates this point. In 1995, Donna Shalala, the Secretary of the Department of Health and Human Services, significantly abrogated both the number of Table-recognized injuries (eliminating seizure and shock collapse disorders and redefining brain injury and inflammation) and reduced the timing requirements (requiring anaphylactic shock to occur within four hours of immunization). See John Hanchette & Sunny Kaplan, An Abysmal Failure, CINCINNATI INQUIRER, Aug. 31, 1998, available in 1998 WL 3785443; see also Terran v. Secretary of the Dep't of Health and Human Servs., 41 Fed. Cl. 330, 335 (1998) ("Retroactive application of Table revisions allows cases to be decided using the most accurate causation information, regardless of when the injury occurred.").
alleges a Table injury within the time period specified by the Table in order to receive a presumption of causation or attempts to establish causation-in-fact, the petitioner's ability to recover is highly dependent upon the facts surrounding the administration of the injury-producing vaccine.\footnote{142}

Congress recognized the importance of such factual determinations when it enacted the Act in 1986.\footnote{143} It initially considered the creation of an administrative agency or other extra-judicial body to handle petitioners' claims.\footnote{144} Congress also entertained the creation of a hearing process through which a petitioner would be bound by the decision of a panel composed of persons selected by the Secretary of Health and Human Services.\footnote{145} Eventually Congress focused on administering the Act through the existing court system and created the Office of the Special Master in order to administer the fact finding required by the Act.\footnote{146}

Though this Note addresses the overwhelming problems of the Act, specifically the dangers associated with special masters' powerful discretion, achievement of the Act's goals is not impossible. First, and perhaps most drastically, the Act could be completely restructured. Instead of having an entirely court-based process, administration of the Act could be founded in an extra-judicial body or an administrative agency, as Congress had considered originally.\footnote{147} Nevertheless, because such an approach would constitute a complete overhaul of the Act, an alternative solution should be considered.

Rather than implement an entirely new process for recovery under the Act, Congress could revamp the current process by clearly stating the standard of review to be applied on appeal. Though the Act requires review of a special master's decision by

\footnote{142. See Bradley v. Secretary of the Dep't of Health & Human Servs., 991 F.2d 1570, 1577 (Fed. Cir. 1993) (Plager, J., concurring in part and dissenting in part).}
\footnote{143. See Munn v. Secretary of the Dep't of Health & Human Servs., 970 F.2d 863, 868 (Fed. Cir. 1992).}
\footnote{144. See id.}
\footnote{145. See id.}
\footnote{146. See id. Congress initially granted jurisdiction to the federal district courts, but upon reconsideration created the Office of the Special Master within the Federal Claims Court. See id.}
\footnote{147. See id.}
the Court of Federal Claims under an arbitrary and capricious standard,\(^\text{148}\) it does not clearly require a specific standard of review for appeals to the Federal Circuit Court of Appeals.\(^\text{149}\) Although many courts follow the decision in \textit{Munn}, which determined that Federal Claims Court decisions are subject to the same arbitrary and capricious standard of review by the Federal Circuit Court,\(^\text{150}\) a type of review similar to that found in International Trade Commission (ITC) decisions is viable.\(^\text{151}\) Under this scenario, the Federal Circuit Court of Appeals would directly review the decision of the special master and would not limit its review to the decision of the Court of Federal Claims. Although the standard would remain one requiring arbitrariness or capriciousness, the court would directly review the decision of the special master, not indirectly through a review of the Federal Claims Court decision.\(^\text{152}\)

There are several reasons why this latter alternative could enhance the effectiveness of the Act. First, direct review of special masters’ decisions by both the Court of Federal Claims and the Federal Circuit Court of Appeals could serve as an additional check against the power of the special master previously discussed in this Note. Second, the additional scrutiny of the court of appeals could aid the consistency with which petitioners recover under the Act.

Nevertheless, employing such a standard of review will not serve as a cure-all to the Act. It will not affect the over- and under-inclusiveness of the Table. As stated previously, this approach would continue to require the reviewing court to find a special master’s decision arbitrary or capricious in order to re-

\(^{148}\) See 42 U.S.C. § 300aa-12(e)(2) (1994); see also \textit{Munn}, 970 F.2d at 869 (describing that a Federal Claims Court may set aside a special master's findings of fact or conclusions of law only when they are arbitrary or capricious).

\(^{149}\) See \textit{Munn}, 970 F.2d at 869; supra text accompanying notes 106-09.

\(^{150}\) See \textit{id.} at 870 ("[W]e may not disturb the judgment of the Claims Court unless we find that judgment to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.").

\(^{151}\) See \textit{Bradley v. Secretary of the Dep't of Health & Human Servs.}, 991 F.2d 1570, 1577 (Fed. Cir. 1993) (Plager, J., concurring in part and dissenting in part).

\(^{152}\) See \textit{id.} at 1577-78 (describing that the decisions of the ITC are reviewed first by the Court of International Trade (CIT), and then reviewed by the Federal Circuit as if no intermediate review by the CIT had taken place).
verse that decision. In a system completely dependent on factual determinations, however, it may serve to enhance the fairness of the Act without further compromising its efficiency.

CONCLUSION

A brief return to the Clements family highlights the general problems of the Act expounded in this Note. As described above, the special master presiding over Andrew's claim denied recovery. Though Special Master Millman found the case "tragic," she concluded the Clements family had not demonstrated that Andrew's DPT vaccines were the cause-in-fact of his injuries. Stating that she "sympathizes with the Clements family for their situation," Special Master Millman concluded her decision by noting that "petitioners may prevail solely on the evidence they present, not on the sympathy they engender." All sympathy aside, in slightly different but similar circumstances, Andrew might have recovered under the Act. In a different year or through the review of a different special master, the evidence the Clements family presented could have been deemed sufficient. Though Special Master Millman found the Secretary's expert more credible than the experts testifying for the Clements family, another special master may have reached a different conclusion. Such a favorable determination would have supported a finding that Andrew's injuries were caused by his DPT vaccine. Nevertheless, the unbridled discretion afforded the special masters and criticized in this Note facilitates these inconsistencies.

In addition, Andrew may have been able to recover had the claim been filed prior to a 1995 revision in the Table. Under earlier regulations, Andrew's seizure disorder and encephalopathy were recognized by the Vaccine Injury Table. The present regulations have eliminated the residual seizure disorder from

154. Id.
155. See id. at *11-*12.
the Table and have modified the symptoms required for encephalopathy to be recognized by the Table.\textsuperscript{158} Unfortunately, the Clements's filed their petition after the changes in the Table became effective. Thus, they could prevail only by proving causation-in-fact.\textsuperscript{159} The Clements family's situation further brings to life the problems with the Table identified in this Note.

Finally, Andrew's troubles may not be over. Though his family may request review by the Court of Federal Claims and may further appeal to the Federal Circuit Court of Appeals, the likelihood that he will succeed is doubtful. Until the appellate courts become willing to review the findings of the special master with greater skepticism, children like Andrew Clements will gain nothing more than a guarantee that they will not contract a vaccine-preventable illness. This is an extremely high price to pay given the emotional and physical toll the vaccine takes on the families of children who suffer the adverse reactions.

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\textsuperscript{158} See Clements, 1998 WL 481881, at *16 n.2.
\textsuperscript{159} See id.